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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,618	12/29/2006	Menachem Kraus	U 016272-1	5404
140 7590 03/24/2011 LADAS & PARRY LLP 1040 Avenue of the Americas NEW YORK, NY 10018-3738				
EXAMINER MAUST, TIMOTHY LEWIS				
ART UNIT 3751		PAPER NUMBER		
NOTIFICATION DATE 03/24/2011		DELIVERY MODE ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/577,618

Applicant(s)

KRAUS ET AL.

Examiner

Timothy L. Maust

Art Unit

3751

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 64-95 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 64-95 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-940)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 4/28/06, 9/1/06, 3/25/09, 8/2/10, 3/8/11
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, Claims 64-95 in the reply filed on 3/8/11 is acknowledged.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

((b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 64-67, 70, 71, 73-77, 79-84, 86-90 and 92-95 are rejected under 35 U.S.C. 102(b) as being anticipated by Russo (6221041).

Regarding claim 64, 83, the Russo reference discloses a drug mixing system (see Figure 2) comprising:
at least one receptacle port adaptor (12 and needle 2) adapted to be inserted into a port of a fluid receptacle (IV bag); at least one vial adaptor (housing 16) adapted for

connection to a vial containing a drug; and at least one syringe adaptor (5) adapted to be attached to a syringe (not shown) and to at least one of said at least one receptacle port adaptor and said at least one vial adaptor (via 3 way valve (3)), said system being characterized in that at least one of said at least one receptacle port adaptor, said at least one syringe adaptor and said at least one vial adaptor being vented to the atmosphere (via filter (14)) in a manner which prevents release to the atmosphere of possibly harmful contents of said vial. Further, at least one syringe adaptor is adapted to be brought into fluid communication and mechanically locked to at least one of said at least one receptacle port adaptor and said at least one vial adaptor in a single step. The syringe is locked to the apparatus via a luer lock (see column 4, lines 63-65).

Regarding claims 65 and 66, wherein said possibly harmful contents of said vial are in a liquid, solid or gaseous form. Filter (14) filters gas and micro-organisms.

Regarding claim 67, also comprising a membrane vent (15) operative to vent at least one of said at least one receptacle port adaptor, said at least one syringe adaptor and said at least one vial adaptor to the atmosphere.

Regarding claim 70, see column 5, lines 45-49.

Regarding claims 71 and 84, wherein said receptacle port adaptor, said syringe adaptor and said vial adaptor are integrally formed. Further, the patentability of a product does not depend on its method of production. If the product in the claim is the same as or obvious from a product in the prior art, the claim is unpatentable even though the prior product was made by a different process (see MPEP 2113).

Regarding claims 73, 74, 86 and 87, see column 4, lines 10-15.

Regarding claims 75 and 88, wherein said needle port adaptor (2 and 12) includes a locking mechanism (20 and 21), operative to lock said needle port adaptor to said needle port.

Regarding claims 76 and 89, wherein said needle port adaptor includes a needle (2), said needle being protected by a needle protector (10).

Regarding claim 77 and 90, wherein said needle is movable between a protected resting position (i.e., when the cap is on) and an active piercing position (i.e., when the cap is removed and the needle pierces an IV bag) upon connection of said needle port adaptor to said needle port.

Regarding claims 79 and 92, further comprising a vial head adaptor (spike 1) adapted for connection between said vial adaptor and said vial.

Regarding claims 80 and 93, wherein said at least one receptacle port adaptor and said fluid receptacle are adapted to be connected to an intravenous cannula on a patient via an intravenous infusion set. The Russo device is capable of being connected to an IV cannula on a patient.

Regarding claims 81 and 94, wherein said at least one syringe adaptor and said syringe are adapted to be connected to an intravenous cannula on a patient via an intravenous infusion set using an infusion set adaptor. The syringe of the Russo device is capable of being connected to an IV cannula on a patient as long as the connection is a luer lock.

Regarding claims 82 and 95, wherein said at least one syringe adaptor is covered by a syringe adaptor cover element (see screw cap 11 in Figure 2).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 68, 69, 78 and 91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Russo.

The Russo reference discloses the invention as claimed (discussed supra), but doesn't disclose the membrane vent (15) being made of a carbon cloth and the needle protector (10) being made of a latex. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the Russo membrane and needle protector of a carbon cloth and latex, respectively, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416

Claims 72 and 85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Russo.

The Russo reference discloses the invention as claimed (discussed supra) including housing (16), but doesn't disclose the protective vial housing (housing 16; see col. 5, lines 55-59) being operative to prevent the spread of possibly harmful contents of

said vial in the event of breakage of said vial. However, the Examiner takes Official Notice that housings are well known and used in the art to protect vials from breakage. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Russo device to have a housing for the vial in order to protect it from breakage.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The prior art of record pertains to various transfer devices, similar to applicant's device.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy L. Maust whose telephone number is (571) 272-4891. The examiner can normally be reached on Mon. - Thur. 7:00-5:30pm.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Timothy L Maust/
Primary Examiner
Art Unit 3751

3/16/11